BIOMET MICROFIXATION

OCT 12 2012

510(k) Summary

510(k) Number: K121624
Date Prepared: October 2, 2012
Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Contact: Sheryl Malmberg, Global Regulatory Affairs Specialist
904-741-4400 fax 904-741-9425

Common or Usual Name:	Neuro Plating System		
Classification Name:	Preformed Alterable Cranioplasty Plate	Burr Hole Cover	Cranioplasty Plate Fastener
Device Classification:	II (882.5320	II (882.5250)	HBW (882.5360)
Device Product Code:	GWO	GXR	HBW

Device Name: Biomet Microfixation Neuro Plating System

Intended Use:

These devices are implantable bone plates and bone screws for neuro procedures including:

1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed

Contraindications:

1. Active infection
2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection.
4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Description: Biomet Microfixation manufactures and distributes a variety of internal fixation devices intended to aid in the alignment and stabilization of bone in the cranial skeletal system. Instrumentation has been designed specifically for use with each system of implants.

The Biomet Microfixation Cranio/Neuro Plating System is comprised of a variety of titanium plates and screws with shapes and sizes intended to aid in the alignment and stabilization of bone in the cranial skeletal system.

The plates include variations of straight, angle, double angle, L-shape, T-shape, Z-shape, X-shape, burr hole, triangle, square, matrix, mesh, and crescent options with various lengths and thickness. The screws range in diameters of 1.0mm to 2.3mm and lengths from 3.0mm to 6.0mm.

Sterility Information: The plates and screws will be marketed as non-sterile, single use devices.

Possible risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.

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Substantial Equivalence Biomet Microfixation considers the Neuro Plating System modifications equivalent to the Biomet Microfixation (formally Walter Lorenz Surgical) Wuerzburg Titanium Mini Bone Plates and Bone Screws cleared under K854886, Lorenz 1.0 MM System cleared under K922741, and Lorenz 1.0mm, 1.5mm, 2.0mm Plating system cleared under K953385. Subject pre-contoured mesh are similar to the predicate devices in terms of material, indications, use, sterility, and design.

	Biomet Microfixation Neuro Plating System	**Walter Lorenz Surgical K854886**	**Walter Lorenz Surgical K922741**	**Walter Lorenz Surgical K953385**
Material	Titanium	Titanium	Titanium	Titanium
Indications for Use	These devices are implantable bone plates and bone screws for cranial procedures including: 1. Fractures 2. Osteotomies 3. Reconstructive procedures 4. Revision procedures where other treatments or devices have failed.	These devices are implantable bone plates and bone screws for oral, cranio-maxillofacial procedures including: 1. Fractures, 2. Osteotomies, including orthognathic procedures, 3. Reconstructive procedures, and 4. Revision procedures where other treatments or devices have failed.	These devices are implantable bone plates and bone screws for oral, cranio-maxillofacial procedures including: 1. Fractures, 2. Osteotomies, including orthognathic procedures, 3. Reconstructive procedures, and 4. Revision procedures where other treatments or devices have failed.	These devices are implantable bone plates and bone screws for oral, cranio-maxillofacial procedures including: 1. Fractures, 2. Osteotomies, including orthognathic procedures, 3. Reconstructive procedures, and 4. Revision procedures where other treatments or devices have failed.
Use	Single	Single	Single	Single
Sterility	Provided non-sterile; steam sterilization validation on file	Provided non-sterile; steam sterilization validation on file	Provided non-sterile; steam sterilization validation on file	Provided non-sterile; steam sterilization validation on file
Shape of Plates	New shape includes pre-contoured mesh. Additional system plates include variations of straight, curved, angle, double angle, L-, T-, double T-, Z-, X-, Y-, double Y-shape, burr hole, triangle, rectangle, square, matrix, and mesh options with various lengths and thicknesses.	Variations of straight, curved, L-, T-, Y-shape, matrix, plate options.	Variations of straight, square, rectangular, and mesh plate options	Variations of straight, angle, curved, L-, T-, double T-, Z-, X-, Y-, double Y-, H-shape, triangle, square, rectangle, matrix, mesh, orbital floor, and LeFort plate options.
Screw Sizes	No new screws in this submission. Additional system screws range in diameters of 1.0mm to 2.3 and lengths from 2.0mm to 7.0mm. Head geometry includes cross-drive and center drive, with HT (high torque) and SD (self-drilling) options.	Screws range in diameters of 1.0mm to 2.3mm and lengths from 2.0mm to 29.0mm Head geometry includes cross-drive and center drive, with HT (high torque) and SD (self-drilling) options.	Not Applicable	Not Applicable

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Nonclinical testing: Referenced testing demonstrates that the device can be cleaned and sterilized within the required parameters, demonstrating equivalence to the predicate devices. A worst case scenario of instrumentation was compromised and underwent testing resulting in achieving the required cleaning results as outlined in the testing. The cleaning testing was performed per an FDA approved protocol. Sterility testing, (Reference AAMI TIR 12 and ANSI/AAMI/ISO 17665-1:2006) provided worst case testing by inoculating worst case sample components that then demonstrated results to have been effectively sterilized per required parameters.

Conclusion: This testing data supports the determination of substantial equivalence by demonstrating worst case scenarios for both cleaning and sterilization that fall within acceptable parameters providing a 10^{-6} Sterility Assurance Level (SAL). No new safety and efficacy issues were raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2012

Biomet Microfixation
% Ms. Sheryl Malmberg
Global Regulatory Affairs Specialist
1520 Tradeport Drive
Jacksonville, FL 32218

Re: K121624
Trade/Device Name: Biomet Microfixation Neuro Plating System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: September 11, 2012
Received: September 12, 2012

Dear Ms. Malmberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121624

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These devices are implantable bone plates and bone screws for neuro procedures including:
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Prescription Use __xx_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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